Report on Pharmacy Liaison Committee and Drug Utilization Review Board

Virginia Department of Medical Assistance Services
December 2007

I. AUTHORITY FOR REPORT

Item 302 (I) of the 2007 Appropriations Act directs the Department of Medical Assistance Services (DMAS) to implement continued enhancements to the prospective drug utilization review (ProDUR) program. DMAS is directed to continue the ProDUR Committee and the Pharmacy Liaison Committee in order to promote the implementation of cost effective initiatives within the Medicaid pharmacy program. The Appropriations Act further requires DMAS to report on the activities of these Committees to the Board of Medical Assistance Services, the Department of Planning and Budget, and the Chairmen of the House Appropriations and Senate Finance Committees by December 15 of each year.

II. BACKGROUND

A. Role of the DUR Board

The Drug Utilization Review Board, hereafter, ("the DUR Board") is an expert panel composed of physicians, pharmacists and nurse practitioners appointed by the DMAS Director. In this capacity, the DUR Board defines the parameters of appropriate medication use within federal and state guidelines; meets periodically to review, revise and approve new criteria for the use of prescription drugs; and, develops drug utilization review criteria by addressing situations in which potential medication problems may arise, such as high doses, drug-drug interactions, drug-diagnosis interactions, adverse drug reactions, and therapeutic duplication.

The DUR Board consists of two programs (1) the prospective DUR (ProDUR) and (2) the retrospective DUR (RetroDUR). The intent of both programs is to help ensure the health and safety of patients.

The ProDUR program involves a review of prescription and medication orders and patients' drug therapy history prior to prescription orders being filled. The ProDUR program allows pharmacy claims to be evaluated at the time claims are actually submitted. Specifically, the ProDUR program is an interactive on-line, real-time process in which pharmacy claims are evaluated for potential problems related to established criteria for appropriate use (e.g., drug-drug interactions). Due to the short turn-around time associated with point-of-sale processing (30 seconds or less per transaction), immediate alert messages are sent to pharmacists on the most serious potential concerns based on a hierarchy of risks that is continually reviewed by the DUR Board. A pharmacist, based on clinical judgment, can override ProDUR alerts. In these cases, the pharmacist needs to provide justification or claims will be denied.

Unlike the ProDUR program which is prospective in nature, the RetroDUR program retroactively examines medication utilization (claims data) to identify potentially problematic patterns (e.g., non-compliance, excessive quantities, etc). After the DUR Board decides which drug classes they want to evaluate, the appropriate claims data are extracted. Then an expert panel of reviewers evaluates a sample of the claims data to identify potentially problematic prescribing practices. When these practices are noted, the expert panel requests that the program contractor mail educational intervention letters to pharmacies and/or providers. The educational letters ("patient profile letters") are customized to each identified case.

B. New DUR Board Members Selected in 2007

In 2007, DMAS filled three vacancies on the DUR Board due to term expirations. The following candidates were selected for the Board: (1) James Evans, MD, a psychiatrist with the Department of Mental Health, Mental Retardation, and Substance Abuse Services; (2) Michele Thomas, PharmD, also with the Department of Mental Health, Mental Retardation, and Substance Abuse Services; and (3) Cindy Fagan, a Nurse Practitioner with McGuire VA Medical Center.

III. KEY DUR BOARD ACTIVITIES IN 2007

A. Criteria Reviews and Updates

The DUR Board met two times in 2007 (April and August). During these meetings, the DUR Board approved criteria for new drugs, revised and approved criteria for existing drugs, and updated existing criteria. Anytime the DUR Board approves new criteria or revises criteria, the criteria are integrated into both the ProDUR and the RetroDUR programs. Criteria reviewed in 2007 are summarized below.

Criteria for new drugs. In 2007, the DUR Board reviewed and approved criteria for 11 new drugs, including:

- Aliskiren (Blood pressure drug);
- Paliperidone (Atypical Antipsychotic);
- Sitagliptin (Antidiabetic);
- Sitagliptin/Metformin (Antidiabetic);
- Telbivudine (Antiviral); and
- Vorinistat (Antineoplastic).

Revised and approved criteria for existing drugs. In 2007, the DUR Board reviewed and approved criteria for (1) Growth Hormones (to accelerate growth, growth deficiency, and multiple uses); (2) Hepatitis C Agents (Hepatitis C); and (3) Low Molecular Weight Heparins (LMWH) (Anticoagulant).

Updated existing criteria. In 2007, the DUR Board reviewed and updated existing criteria for the following therapeutic classes:

- Antidepressants;
- Antihypertensives;
- Antipsychotics;
- Antiviral agents;
- Narcotic analgesics;
- Oral hypoglycemic agents (diabetes drugs);
- Lipotropics (cholesterol drugs);
- Antiarrhythmics (heart drugs);
- Diuretics (heart/blood pressure drugs); and
- Quinolones (antibiotics)

B. Cost and Utilization Reports Reviewed

In addition to reviewing clinical criteria, during the 2007 DUR Board meetings, the Board reviewed quarterly cost and utilization reports prepared by the program contractor (First Health Services Corporation). The DUR Board also reviewed ProDUR program cost savings reports and summaries of ProDUR alerts.

In April 2007, the DUR Board also reviewed utilization reports on Fentora (Narcotic analgesic), Narcotics, Zelnorm (Gastrointestinal Drug), Smoking Cessation, and Quetiapine (Antipsychotic). The utilization reports were based on data from November 1, 2006 to January 31, 2007.

C. RetroDUR Program Activities

1. RetroDUR Reviews

Between October 2006 and December 2007, the DUR Board retroactively reviewed patient profiles and mailed letters on the following items:

- Criteria exceptions for the new drugs approved by the Board at the August 2006 meeting;
- Non-compliance with ACE inhibitor (heart drugs) therapy;
- Non-compliance with Beta Blocker (heart drugs) therapy;
- Non-compliance with Lipotropic (cholesterol) therapy in post-myocardial infarction patients;
- Acetaminophen (analgesic) overutilization;
- Beer's List Criteria (defined below);
- Polypharmacy (defined below);
- New drugs approved by the Board at the November 2006 and August 2007 meetings;
- FDA Warning regarding the risks of Sedative-Hypnotic agents;
- FDA Warning regarding cardiovascular risks associated with rosiglitazone (diabetic drug);
- Re-review of Long-acting Beta Agonist (respiratory drugs) FDA Public Advisory;
- Re-review of the empiric use of antibiotics to treat upper respiratory tract infections;
- Re-review of Rosiglitazone (diabetic drug) FDA Warning regarding risk of macular edema;
- Re-review of ACE Inhibitors (heart drugs) use not recommended during pregnancy;
- Re-review of Telithromycin (antibiotic) FDA Public Advisory; and
- Re-review of HIV Medication Non-compliance

Providers and pharmacists can respond to the educational letters to formally acknowledge that they received and reviewed the patient profile letter. Potential responses providers and pharmacists can provide include:

- Aware of situation and no adjustment to current therapy is necessary at this time;
- Plan to discontinue medication(s);
- Information clinically useful and plan to alter treatment regimen for specified patient;
- Information clinically useful and plan to monitor or counsel specific patient;

- Plan to change dose;
- Information regarding patient or provider appears to be incorrect; or
- Other (additional comments may be added by prescribers)

Seven months after the letters are mailed to providers and/or pharmacists, the DUR Board conducts re-reviews based on claims data to assess whether providers and pharmacists accepted recommended changes resulting in increased compliance to accepted treatment guidelines.

A RetroDUR response rate is calculated by dividing the number of responses received by the number of patient profile letters that were mailed. Between October 2006 and June 2007, 1,412 letters were mailed to providers and pharmacists and 309 responded. This equates to a 22 percent RetroDUR response rate.

2. Beers List Criteria

The 2003 Virginia General Assembly passed legislation that required DMAS to review its elderly long-term care enrollees for inappropriate use of medications as defined by Dr. Mark Beers. Dr. Beers has published several articles describing the inappropriate use of various medications in older adults. With the implementation of Medicare Part D, Medicaid no longer covers the majority of the medications on the "Beers List" for dual eligibles (Medicaid enrollees who are also Medicare eligible). However, two major classes of drugs, benzodiazepines and barbiturates (sedatives), are excluded by Medicare, so they are still covered by Medicaid. Additionally, Medicare Part D does not cover over-the-counter (OTC) medications. Consequently, OTC medications, such as antihistamines and decongestants, are included in the Beers criteria.

In May 2007, the DUR Board retroactively reviewed medications on the "Beers List". Based on their review, the DUR Board discovered that:

- 22 percent of the inappropriate use criteria interventions involved the use of benzodiazepines in doses that exceeded the recommended maximum for older adults;

- 28 percent involved the use of benzodiazepines or barbiturates that are inappropriate to use in older adults at any dosage;

- 31 percent of the interventions involved the use of benzodiazepines that are not recommended in patients with certain medical conditions; and

- 15 percent involved the inappropriate use of the over-the-counter antihistamine, diphenhydramine, as a sedative-hypnotic.

Inappropriate use of these medications can lead to prolonged sedation and an increased incidence of falls and fractures in older adults. As a result of their review, in June 2007, the DUR Board sent letters to prescribers whose patients were receiving these medications. Eighty-five letters were sent. DMAS will report the number of prescribers that responded to these letters in the 2008 annual report.

3. Polypharmacy

Polypharmacy occurs when patients receive multiple prescriptions from multiple prescribers and have their prescriptions filled at multiple pharmacies. Polypharmacy may occur when patients lack a primary care physician and/or a single pharmacy to coordinate and optimize their medication regimen. Polypharmacy can be problematic because it places patients at an increased risk of adverse medication-related events. This is often seen in older adults because this segment of the population often experiences the greatest number of co-morbid diseases that require multiple prescribers and medications.

DMAS has seen a decline in polypharmacy criteria violations since Medicare Part D (which is focused on older adults) was implemented. Polypharmacy, however, still exists in the remaining population and prescribers seem receptive to the information they receive.

In April 2007, a polypharmacy review was incorporated into the existing RetroDUR program. The intent of the review was to evaluate patients (1) who receive more than nine unique prescriptions in a 34-day period and (2) whose prescriptions were written by 3 or more prescribers and filled at 3 or more pharmacies. Approximately 6,000 patient medication profiles were reviewed for polypharmacy and a total of 802 intervention letters were sent to prescribers.

The overall prescriber response rate for the polypharmacy RetroDUR program was 22 percent; of those responding, 76 percent indicated that they find the information useful and plan to monitor, alter or discontinue the treatment regimen.

IV. COSTS AVOIDED AS A RESULT OF DRUG UTILIZATION REVIEWS

Drug utilization review programs are valuable tools to monitor and guide healthcare management. Cost savings for drug utilization programs are essentially cost avoidance figures. For example, as part of the ProDUR program, the savings on a denied early refill claim is realized at point of sale, but is then lost if the patient returns the following week for his/her refill. As part of the RetroDUR program, if a patient is no longer enrolled in Medicaid, the lack of drug usage is interpreted as a change in therapy and thus a cost savings. Therefore, use of such a calculation can lead to an inflated estimate of savings because the therapy may not have actually been changed. Consequently, drug utilization review programs should be viewed as a quality of care initiative rather than actual cost containment programs.

V. OTHER MEDICAID PHARMACY INITIATIVES REVIEWED BY THE DUR BOARD

A. Behavioral Pharmacy Management System

In April 2005, DMAS, in partnership with the Department of Mental Health, Mental Retardation, and Substance Abuse Services (DMHMRSAS), implemented a new pharmacy quality initiative, the Behavioral Pharmacy Management System (BPMS) program. The BPMS is administered by Comprehensive NeuroScience (CNS) and supported by Eli Lilly and Company. The BPMS program has been implemented in more than 25 states since 2003. According to CNS, there is evidence that total pharmacy costs associated with behavioral health drugs has decreased for patients whose physicians receive an intervention from CNS.

The BPMS provides a retrospective review of behavioral pharmacy claims and delivers interventions to Medicaid providers whose prescribing practices do not meet best practice guidelines. As directed by Appropriations Act language, antipsychotic drugs, antidepressants, and anti anxiety medications are excluded from DMAS' Preferred Drug List. This increases the value of participating in the BPMS program to review behavioral health medications. Virginia's involvement in the BPMS program is supported by the Psychiatric Society of Virginia.

DMAS continued the BPMS program in 2007 with renewed funding from Eli Lilly. The upgraded 2007 version of the BPMS program includes system enhancements aimed at reducing false positives. In 2007, the average monthly response rate was 12 percent on the prescriber mailings. In 2007, DMAS also worked closely with the Psychiatric Society of Virginia and community psychiatrists to develop a team of peer reviewers. The peer reviewers are intended to engage in consultations with prescribers to promote the use of "best practice" guidelines.

During the August 2, 2007 DUR Board meeting, DMAS began transitioning the BPMS program to the RetroDUR program of the DUR Board. As mentioned, James Evans, MD and Michele Thomas, PharmD, both from the DMHMRSAS, were appointed to the DUR Board in 2007. Dr. Evans, a Psychiatrist, and Dr. Thomas, a Psychopharmacologist, both served on the CNS Project Management Team when Virginia began participating in the BPMS program in March 2005. Their appointments are intended to enhance the ability of the DUR Board to perform behavioral pharmacy reviews.

Based on preliminary data, there is no current evidence that overall expenditures for psychotropics have slowed in Virginia since the BPMS intervention began. However, there is evidence that the total behavioral pharmacy costs for targeted patients (those patients whose physicians received an intervention from CNS) is decreasing. DMAS has asked for an additional savings report from CNS and we are awaiting the final report.

B. Dose Optimization and Maximum Quantity Limits Program

DMAS Pharmacy staff presented an enhanced ProDUR program on dose optimization and maximum quantity limits to the Board during the April 26, 2007 and August 2, 2007 Board meetings. These enhanced programs consist of ensuring that recipients have a 34-day supply of a medication with reasonable dispensing quantities.

The dose optimization program identifies high cost products where all strengths have the same unit cost and the standard dose is one tablet per day. By providing the highest strength daily dose, the number of units in a 34-day supply will be minimized. This program will not require "pill splitting" due to the potential medical risks and burden on recipients and pharmacy providers.

Establishing maximum quantity limits involves identifying high cost products where a 34-day supply is defined by a set number of tablets. This strategy establishes quantity limits based on commonly acceptable clinical dosing practices.

During the initial stage of implementation, dose optimization will focus on antipsychotics and ADHD agents. Maximum quantity limits will focus on anti-emetics (anti-nausea/vomiting), anti-

migraine agents, and narcotics. DMAS will continue to review the list of drug classes for opportunities to include new classes for cost savings and quality of care purposes.

The dose optimization and maximum quantity initiatives were implemented using point of sale edits effective July 1, 2007. During the initial stages of the implementation, edits for both programs will be messages only to pharmacy providers rather than claims denials. This method will enable pharmacists to consider the best available option and make decisions based on professional judgment or at the request of a physician. During subsequent stages of implementation, claims denials with prior authorization will be utilized for the dose optimization program, and claims denials with no prior authorizations will be utilized for the maximum quantity limits program. Effective January 1, 2008, claim denials will be made at point of sale for both dose optimization and maximum quantity limits when dispensing is outside of guidelines. The total savings projected for Fiscal Year 2009 across both programs is estimated to be $2.1 million.

VI. PHARMACY LIAISON COMMITTEE ACTIVITIES

The Pharmacy Liaison Committee is comprised of appointed members who meet periodically to discuss pertinent Medicaid pharmacy issues and the impact on the pharmacy community. The Pharmacy Liaison Committee (PLC) includes representatives from (1) long-term care pharmacies; (2) the Pharmaceutical Research and Manufacturers Association (PhRMA); (3) the Virginia Association of Chain Drug Stores (VACDS); and (4) the Virginia Pharmacists Association (VPhA).

On September 24, 2007, the PLC met and heard DMAS staff presentations on tamper-resistant prescription pads, dose optimization and maximum quantity limits, National Provider Identification (NPI) implementation, Average Manufacturer's Price (AMP), and E-Prescribing (Transformation Grant).

The meeting also focused on the implementation of a Specialty Drug Program in Virginia Medicaid. The PLC discussed potential drug classes and conditions that could be addressed through a Specialty Drug program.

For additional information on the Specialty Drug Program, please refer to DMAS' November 2007 annual report to the Virginia General Assembly on the Specialty Drug Program. For information on other pharmacy initiatives, such as the Preferred Drug List and Average Manufacturer Price, please also refer to DMAS' November 2007 annual reports to the Virginia General Assembly.

VII. ACKNOWLEDGEMENTS

DMAS wishes to acknowledge the many health care professionals and industry groups who have participated in the development and implementation of pharmacy program initiatives over the past year.